

Indium (In111) Chloride

370MBq per ml
radiopharmaceutical precursor

¹¹¹In as indium chloride

Read all of this leaflet carefully before this medicine mixed with another component is administered to you because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor. See section 4.

What is in this leaflet:

1. What Indium (In111) Chloride is and what it is used for
2. What you need to know before Indium (In111) Chloride is used
3. How Indium (In111) Chloride is used
4. Possible side effects
5. How to store Indium (In111) Chloride
6. Contents of the pack and other information

1. What Indium (In111) Chloride is and what it is used for

This medicine is for **diagnostic use** only.

Indium (In111) Chloride is used through a scan to examine different parts of your body, depending on the other non-radioactive component used. Your doctor will explain the purpose of use.

This medicine contains a radioactive substance which when mixed with the other component and administered, collects in certain organs.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows the distribution of radioactivity within the organ and body. This also gives the doctor valuable information about the structure and function of that organ.

2. What you need to know before Indium (In111) Chloride is used

Do not use Indium (In111) Chloride

if you are

- allergic to indium chloride or any of the other ingredients. (listed in section 6)

Further information regarding when this medicine should not be used, is provided in the package leaflet of the other component.

Warnings and Precautions

This medicine does involve treatment with radioactivity. Your doctor will only give you this medicine if the benefit outweighs the risk.

Indium (In111) Chloride is given by specialists, who will take responsibility for any necessary precautions.

Your doctor will inform you if you need to take any special precautions after using this medicine. Contact your doctor if you have any questions.

Other medicines and Indium (In111) chloride

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Further information regarding medicines which can influence or be influenced by Indium (In111) Chloride is provided in the package leaflet of the other component.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice.

• Pregnancy and women of childbearing potential

Your doctor will **only** administer Indium (In111) Chloride during **pregnancy or when you might be pregnant if it is absolutely necessary**, as it could harm the unborn child. Your doctor will also give you advice about how long to avoid pregnancy after the treatment.

• Breast-feeding

He/she may **delay treatment** until breast-feeding is finished. He/she may also ask you to **stop breast-feeding** and discard this milk, until the radioactivity is no longer in your body.

Driving and using machines

It is not investigated whether Indium (In111) Chloride impairs the ability to drive and operate machinery.

3. How Indium (In111) Chloride is used

Indium (In111) Chloride will always be used in a hospital or similar setting. It will only be administered to you by qualified people trained to handle radioactive material safely.

Your doctor will decide the Indium (In111) Chloride amount to be used.

The dose administered depends on the medicine which is combined.

The lowest dose possible will be used to produce adequate images.

Children under 18 years

Lower doses are used for children according to their weight, body surface area or age.

Method of use

Information regarding the method of use is provided in the package leaflet of the other component.

Scans are usually taken any time after the injection into a vein, depending on the procedure.

Drink as much as possible the day after treatment. This will prevent active substance gathering in the bladder.

If more Indium (In111) Chloride is given than it should

It is unlikely that overdose will occur as this medicine is given under control by a doctor. However, if this happens you will receive appropriate treatment from your doctor.

If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, Indium (In111) Chloride can cause side effects, although not everybody gets them.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

Any further side effects which may be caused are provided in the package leaflet of the other component.

Reporting of side effects

If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Health Products Regulatory Authority

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Ireland

D02 XP77Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Indium (In111) Chloride

Keep out of the reach and sight of children.

Do not use Indium (In111) Chloride after the expiry date stated on the label.

Hospital staff will ensure that the product is correctly stored below 25°C. After opening the vial the solution must be used within 24 hours and stored in a refrigerator between 2-8°C.

6. Contents of the pack and other information

What Indium (In111) Chloride contains

- The active substance is: Indium (In111) chloride
One millilitre of Indium (In111) chloride contains 370 MBq.
- The other ingredients are: hydrochloric acid, water for injections

What Indium (In111) Chloride looks like and contents of the pack

Indium (In111) Chloride radiopharmaceutical precursor is a clear, colourless solution. It is packaged in type 1 Ph.Eur glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap.

Indium (In111) Chloride radiopharmaceutical precursor is supplied in one vial containing:

- 111 MBq (0.3 ml),
- 185 MBq (0,5ml),
- 370 MBq (1.0 ml),
- 555 MBq (1.5 ml) or
- 740 MBq (2.0 ml).

Marketing Authorisation Holder and Manufacturer

Curium Netherlands B.V.

Westerduinweg 3

1755 LE Petten

The Netherlands

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